* NOTICES *

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2.**** shows the word which can not be translated.
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CLAIMS

[Claim(s)]
1. Electrical Energy Source of Release in Housing and this Housing Electrode Produced so that a Series of Heartbeat Signals Emitted from Patient's Heart Might be Detected (42 68), the memory (16) in this housing -- and -- It consists of a control circuit (12) which is in this housing and is in this electrode and an electric communication link condition. The abnormality heartbeat fluctuation zone in consists of a limitation that the heartbeat fluctuation measured value of at least one piece was chosen during the disease period chosen with the corresponding output method (108) memorized by this memory. It reaches. This control circuit compares with this limitation the means (218) and this measured value which calculate the heartbeat fluctuation measured value in a disease period. A means to choose this output method when this measured value is in this limitation (222), By changing this limitation so that it may have a means (234) to correct this abnormality heartbeat fluctuation zone and this measured value may be included, when this control circuit (12) detects the abnormality heart stroke generated into this patient's heart this measurement of fluctuation between heartbeats -- this -- the implantable medical device (10) characterized by being carried out out of this at least one limitation of measured value.
2. this heartbeat fluctuation the abnormality zone where a zone defines abnormality heartbeat fluctuation, and the normal zone which defines normal cardiac rate fluctuation -- containing -- and -- Implantable medical device given in the 1st term with which the outlying count and the diagnostic activities which are generated in the period which has this heartbeat fluctuation measured value in this abnormality zone, and in this control circuit are maintained at the minimum.
3. Implantable medical device given in the 1st term with which this cure contains one of electric stimulus dispatch of amount of assignment to starting of additional sensing activity, starting of additional statistics algorithm, data collection of increment and starting of signal processing, initiation of counteractive chemical dose, and this patient's heart.
4. Implantable medical supply given in the 1st term with which this cure is started when measured value of this heart rate occurs in this abnormality zone, including abnormality zone where this heartbeat fluctuation zone defines abnormality heartbeat fluctuation condition about this patient's heart, and normal zone which defines normal cardiac rate fluctuation condition about this patient's heart.
5. Medical device given in either of above-mentioned claims which become more even with the minimum implantable among percent of the heartbeat section when this heartbeat fluctuation measurement has period longer than average, average absolute deviation, median, the mode, amplitude mode, fluctuation range, and selection period, standard deviation, range, power-spectrum consistency, or distribution.
6. Implantable medical device given in one of following claims in selection level and correlation in physiological condition that consisted of approach (74) of furthermore sensing patient's physiological condition, and this limitation of this heartbeat fluctuation measurement has been sensed.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
Implantable medical device technical field reacted to heart rate fluctuation analysis This invention relates to the instrument reacted to especially heart rate fluctuation about the implantable medical device for stimulating the heart.
Background technique It was thought that human being's heartbeat was conventionally controlled by classic **********. According to this theory, human being's physiology system acts so that heart rate fluctuation may be controlled and it may be made equilibrium. In fact, the clinician was explaining the former usual heartbeat activity as "rhythm of a regular or normal pulse."
The modern judgment is emitted from such traditional ideology. As for the heart, according to the latest research result, healthy human being is not beating by the regularity of a metronome, either. Rather, the heart shows heartbeat fluctuation far from equilibrium. T.F. Refer to work besides the "it is correlation over a long period of time about fractal scenery:DNA sequence and the fractal heart rate section of physiology and medicine" C.K. pen carried by the work (1994) "the fractal in biology and medicine" by edit of nonene MAHHA others, and 55-65 pages. For example, with an electrocardiogram, fluctuation or heart rate fluctuation of stray nature is seen during rest and sleep. The heartbeat fluctuation generated in an individual average heart rate is known as heart rate fluctuation. Heartbeat fluctuation originates in the sympathy of an involuntary nervous system, and the nonlinear interaction between the parasympathetic nerve in a part. A sympathy autonomic nerve and a subsympathy autonomic nerve are **** (SA) of the heart to some extent.
In order to control a tubercle and an atrioventricular (AV) tubercle, it has big effect on control of a heart rate. These two nervous systems change a heart rate by acting mutually a little. A stimulus of this point and the parasympathetic nerve reduces the rate of a beat of the heartbeat adjustment cell which exists in the nodus sinuatrialis of the heart. It is contrary to it and a stimulus of the sympathetic nerve makes the rate of a beat increase.
According to the opinion of almost all clinicians, fluctuation (usually 0.15Hz or less) of a low heart rate is realized by the input of the parasympathetic nerve and the sympathetic nerve over an S-A node, but if parasympathetic nerve runoff is adjusted, fluctuation of a high heart rate will be realized. Furthermore, according to the research report, the increment and correlation of a sympathetic nerve activity accompanying lowering of a parasympathetic nerve activity and it have heart rate fluctuation lowering. Refer to work "component of the heart rate fluctuation measured during acute-myocardial-infarction recovery" American Heart Association besides J Thomas BIGGA, the 61st volume (1998), and 208-215 pages. With the heart which is unhealthy, for example, is suffering from cardiopathy although it is healthy, and a parasympathetic nerve activity will govern maintenance of a heart rate if the heart in a rest condition is taken for an example, the direction of a sympathetic nerve activity may control a heart rate with large influence.
In the past several years, heart rate fluctuation has come to be increasingly recognized as a diagnosis of the healthy risk of the heart which tends to require human being, and prognostic indication. Consequently, many researches have been turned to heart rate fluctuation. Especially the clinician is investigating about possibility of bringing about information important for precognition of the heart stroke to which heart rate fluctuation drew near. For example, in a certain research, it checked that the low standard deviation value of heart rate fluctuation was the indication of a prognosis with the coronary-arteries sudden death more powerful than acute myocardial infarction in the patient under

recovery. Refer to a work "power spectrum analysis of the heart blood vessel fluctuation in patient who has risk of sudden death from cardiac causes" heart blood vessel electrophysiology meeting magazine besides Albert Mari Ernie, and 5th volume (1994) 274 -286 pages.
About current and heart rate fluctuation having functionality about generating of the actual condition of a patient's heart rate, or a future cardiovascular functional disorder, opinion of ****** is generally in harmony. Much research examinations were conducted and this functionality is actually proved. For example, as compared with a congestive-heart-failure patient's thing, a clear difference is seen in a healthy person's heart rate at the heartbeat section. In this point, a healthy person shows a more complicated fluctuation pattern compared with an unhealthy person.
Furthermore, the research result which specifies the relation of heart rate fluctuation and a heart blood vessel patient's death is seen. It is thought that heart rate fluctuation lowering has the increment in a risk and relation between ventricular fibrillation and heart blood vessel sudden death in current. In a certain research, it has come to a conclusion as follows.
When the risk variable after other so-called infarction (for example, the ventriclus-sinister systolic ejection fraction, the cardiac room arrhythmia, and the clinical variable which are prolonged) is taken into consideration, heart rate fluctuation is the sign important point of death. It becomes independent as **. Heart rate fluctuation is the Holter monitor. He is Li of death from other variables (for example, an average heart rate and ventricle arrhythmia) obtained. The relation with SUKU is deep. Heart rate fluctuation is extension of the systolic ejection fraction again. It is the factor which shows the sign of arrhythmia complication notably.
Refer to work "internal medicine bulletin" 118th volume (1993) 436 -447 pages besides coney M.A.Van Ravenswaaij-Arts.
As already pointed out, a clinician foreknows the onset of heart blood vessel sudden death using heart rate fluctuation. Although the exact cause of heart blood vessel death is not understood thoroughly yet, almost all victims have trouble with their ventricular tachycardia which gets worse to ventricular fibrillation. The researcher has spent the great effort, in order to foreknow the onset and the cause of such ventricle nature rapid arrhythmia. Heart rate fluctuation is one effective value which shows a sign. In the latest research of this field, it is checking that the subsequent death rate or a subsequent ventricular rhythm failure can be foreknown using the increment or reduction of heart rate fluctuation in several weeks after acute myocardial infarction of the beginning. By a certain research, as a result of investigating about 800 patients who survived from acute myocardial infarction, as for the patient of 50 or less mses, heart rate fluctuation has reported [heart rate fluctuation] that the death rate is 3.5 times higher as compared with the patient of 100 or more mses. Refer to work "related with the death rate of increase after lowering heart rate fluctuation and its acute myocardial infarction" American Heart Association 59th volume (1987) 256 -262 pages besides Robert E KURAIGA. The patient of congestive cardiac insufficiency and a coronary-arteries disease also shows lowering of heart rate fluctuation. Refer to work "lowered spontaneity heart rate fluctuation in congestive cardiac insufficiency" American Heart Association 64th volume (1989) 1162 -1167 pages besides KASOROG.
The heart rate section usually has fluctuation of a biological cycle also to the healthy individual who has normal heart rate fluctuation. However, this biological cycle becomes less remarkable [several hours ago] from several minutes of a heart stroke, and may begin to become irregular. For example, the researcher discovered that heart rate fluctuation fell gradually before arrhythmia occurrences time amount. In such a case, if it acts as the monitor of the heart rate fluctuation, the prior precognition means of the heart stroke which drew near to the clinician will be given.
As one advantageous point, measurement of heart rate fluctuation is performed without invading into the body, and is usually carried out certainly. The Holter monitor or electrode attached to the patient measures a heart rate to accuracy dramatically. An electrode usually detects a series of heartbeats for a heartbeat in the R-R section.
Then, statistical datas, such as an average, the median, and a standard deviation, are calculated, and it is used for precognition of a heart stroke. By the one known approach of using heart rate fluctuation, the heartbeat section recorded in the state of the usual heartbeat is compared with the subsequent heartbeat section. The deflection looked at by these two records can be used as fluctuation indication of heart rate fluctuation. In the one example, while a patient shows normal or healthy heart rate

fluctuation, the R-R section is recorded by the Holter monitor. And the algorithm based on an average and standard deviation calculates the single user value memorized by fixed memory. This user value expresses the state of stress of the patient under normal heart rate fluctuation conditions. Then, a patient attaches to a wrist the detector which acts as the monitor of the R-R section in the heartbeat period according to individual, for example, the 100 heartbeats. Termination of this heartbeat period calculates a patient's user value at present, i.e., a state of stress, using a wrist detector and Argo RISUMU. And a user value at present [this] is compared with the user value already recorded on the bottom of a normal heart rate condition. Theoretically, this comparison shows the deflection from normal heart rate fluctuation, and serves as criteria showing a patient's heart state of stress. If big deflection is in the user value of two pieces, it will reflect the big deflection in the autonomic nervous system balance between the sympathetic nerve and the parasympathetic nerve. For example, when it deviates from the user value to which the retentive memory of the user value currently recorded at present was carried out 25% or more, the patient may tend to receive a high stress level by the accompanying abnormal-cardiac-rate fluctuation.

One important weak spot relevant to the approach and device which used heart rate fluctuation is not offering the more advanced algorithmic structure. The typical algorithm for heart rate fluctuation calculates the deflection between 2 persons as compared with the user value already memorized in this user value, after calculating a current user value based on a R-R disease period first. However, the algorithmic structure itself does not change. Therefore, these values are compared with the user value memorized similarly again when a new user value is calculated by future R-R disease periods being told. Thus, as an algorithm, the same threshold parameter which defines heart rate fluctuation of normal and abnormalities is used repeatedly.

Another weak spot relevant to the approach and equipment which used heart rate fluctuation is related with operating of the heart rate fluctuation data which result in a heart stroke. Heart rate fluctuation measuring equipment is often equipped with the memory which operates according to the FIFO approach. This kind of memory stores heart rate data in order, discards the oldest data, and saves the newest input data. However, there is important information about future heart strokes in old data.

Disclosure of invention This invention is ** about the approach and device which evaluate individual heart rate fluctuation, in order to recognize or foreknow a heart stroke. The heart rate fluctuation zone is set up as a definition of individual normal and an abnormality heart sinus nodal rhythm at first. Then, these zones are automatically corrected after the generating backward of a heart stroke, or un-generating. Since it is such a thing, normal and the boundary of an abnormal-cardiac-rate fluctuation definition are specified according to the individual's physiological and cardiology-conditions. When a heart stroke happens, a path until it results in the fit is stored. And a patient's heart rate fluctuation is compared with this path, and the decision about a heart re-fit is made.

In this invention, the heartbeat stimulator which used the microprocessor as the base receives the heartbeat signal from the heart. A heartbeat stimulator calculates the time section which occurs between continuation heartbeats, and obtains heart rate fluctuation measured value from the disease period data of the period set up beforehand. Both the statistical data obtained from the time section and the detection data obtained from a patient's sensor are contained in this disease period data, and a heartbeat stimulator is compared with the heart rate variation zone which defines normal and abnormal-cardiac-rate fluctuation in which heart rate fluctuation measured value was already stored. A suitable cure will be started if the measured value of heart rate fluctuation is in the limit of an abnormal-cardiac-rate variation zone. On the other hand, a cure will not be started if the measured value of heart rate fluctuation is in the limit of a normal heart rate variation zone. However, while heart rate fluctuation measured value is in the limit of a normal heart rate variation zone, when the principal has caused a heart stroke, an abnormal-cardiac-rate variation zone will be corrected and will include the heart rate fluctuation measured value. Thus, the definition of normal and abnormal-cardiac-rate fluctuation is changed according to a specific individual's heart conditions.

If a heart stroke happens, memory also preserves permanently current disease period data and a series of disease period data which result in the fit further. This disease period data of a series of forms [both] the path from usually normal heart rate fluctuation conditions to abnormal-cardiac-rate

fluctuation conditions.
This path serves as an aid of decision of precognition of future heart stroke generating, and current heart stroke generating.
All the heart rate variations that occur after this point and a heart stroke are compared with this path. It becomes clear whether have experienced again the same conditions to which a principal results in a former heart stroke by this comparison.
Furthermore, it is divided into the abnormality subzone of plurality [point / advantageous / zone / abnormal-cardiac-rate fluctuation]. Each subzone corresponds to the cure for starting the monitor on the further detection or a therapy. Moreover, the structure which the positiveness of a therapy and the degree of a monitor increase gradually may be included in the cure.
Alternative activation of a cure also serves as power saving in order to make unnecessary energy expenditure and diagnostic activities minimum.
Therefore, this invention consists of the tool and approach of having the structure illustrated by the following detail explanation, the combination of an element, and arrangement of components. In order to understand the property and the object of this invention more nearly thoroughly, please refer to the following detailed explanation relevant to an attached drawing.
Easy explanation (c) drawing 1 of a drawing (it is the block diagram of an implantable heartbeat stimulator.)
(c) Drawing 2 (it is the system diagram showing a heart rate fluctuation parameter in detail.)
(c) Drawing 3 (it is the perspective view of a heart rate fluctuation zone.)
(c) Drawing 4 (it is the block diagram of a cure.)
(c) Drawing 5 (it is the system diagram of disease period statistical-data count.)
(c) Drawing 6 (it is the system diagram of disease period detection data count.)
(c) Drawing 7 (it is the system diagram which compares the heart rate fluctuation parameter remembered to be disease period data.)
(c) Drawing 8 (it is the perspective view of a correction heart rate fluctuation zone.)
(c) Drawing 9 (it is the system diagram which compares the disease period data remembered to be the present disease period data.)
(c) Drawing 10 (it is the perspective view of a series of disease period data which result in a heart stroke.)
The best gestalt for inventing Drawing 1 is the block diagram of the implantable heartbeat stimulator 10 for carrying out this invention. A stimulator 10 shows a pacemaker, a defibrillator, or other implantable heartbeat generators. A microprocessor 12 is control / count category of a stimulator 10. A microprocessor 12 has input/output port which connects with memory 16, the A-V section timer 18, and the pacing section timer 20 by the usual approach through a bi-directional bus 14. The A-V section timer 18 and the pacing section timer 20 have the output connected to the input port where a microprocessor 12 corresponds according to an individual through a line 22 and a line 24, respectively.
A-V and the pacing section timers 18 and 20 are installed in the exterior or the interior of a microprocessor 12 so that it may be illustrated. Furthermore, these timers are the common type up/down counters of the class which calculated value is loaded first, and is counted up or downed and outputs a carry-over bit from this value at the time of the programmed count termination. The first calculated value is loaded to A-V and the pacing section timers 18 and 20 of a bus 14. Each carry-over bit is outputted to the microprocessor 12 of lines 22 and 24. If possible, memory 16 shall contain both ROM and RAM. Usually, ROM memorizes an actuation routine and RAM memorizes a programmable parameter and a variable.
A microprocessor 12 shall have input/output port which connects with the telemetering interface 26 through a line 28 if possible again. Therefore, if transplanted, a stimulator 10 receives a variable and a control parameter from an external programmer, and when required, it can transmit data to an external receiver. Thus, the operation parameter memorized by the microprocessor 12 can be chosen and changed, without invading into the body. This contractor has many well-known telemetering systems. An example of a telemetering system and the coding approach is indicated by U.S. Pat. No. 4,539,992 [/ else / Calfee / which was entitled the open "open approach and tool" which communicate with a transplantation body functional-stimulus machine in September, 1985].

Control lines 30 and 32 connect a microprocessor output port to atrium stimulus heartbeat generator 34 input and ventricle stimulus heartbeat generator 36 input, respectively. Heartbeat parameter data, such as amplitude, width of face, enabling/disable, and a heartbeat activation code, are transmitted to generators 34 and 36 through lines 30 and 32, respectively. Moreover, control lines 38 and 40 connect microprocessor input port to atrium sense amplifier 42 and ventricle sense amplifier 44 output, respectively.

The input of the atrium sense amplifier 42 and the output of the atrium stimulus heartbeat generator 34 are connected to the 1st conductor 46 linked to the 1st common type lead 48. Electric conduction pacing / sensing chip 52 is located in the end of lead 48. This pacing / sensing chip are electrically connected to a conductor 46. For example, it connects with the heart 50 of a right atrium 54.

The input of the ventricle sense amplifier 44 and the output of the ventricle stimulus heartbeat generator 36 are connected to the 2nd conductor 56 linked to the 2nd common type lead 58. Electric conduction pacing / sensing chip 62 is located in the end of lead 58. It connects with a conductor 56 electrically, for example, this pacing / sensing chip are connected to the heart 50 of a right ventricle 60. It passes through leads 48 and 58 into the heart 50, and they are inserted by the vein or other suitable approaches.

Conductors 46 and 56 tell the stimulus heartbeat generated with an atrium and the atrium stimulus heartbeat generators 34 and 36 to pacing / sensing chips 52 and 62, respectively. Pacing / sensing chips 52 and 62, and the corresponding conductors 46 and 56 also tell the heart electrical signal which the heart has sensed to an atrium and the ventricle sense amplifiers 42 and 44.

The heart stimulator 10 can also be used as a defibrillator. A microprocessor 12 controls the high-tension defibrillator circuit 64 about this point. The high-tension leads 66 and 68 of two are connected to the heart with two electrodes 70 and 72. The epicardium patch electrode is shown by the diagram in the illustrated example. however, mind -- other well-known electrode gestalten are used by a sex electrode or this contractor.

Moreover, the input and output port of a microprocessor 12 are also connected to the various sensors 74 through the congruence directional-control bus 76. A sensor or sensing capacity is often used for an implantable heartbeat stimulator. Sensors 74 are the various sensing equipments of the information gathering about a patient. These SANSA senses ventilation, acceleration, an activity, oxygen RE ** RU, blood pressure, temperature, blood oxygenation, the hydrogen ion exponent in blood, an impedance, adrenaline level, etc.

this invention -- various kinds -- it is well-known data for this contractor to be used with the stimulator 10 in drawing 1 shown as an example of an implantable instrument and such an instrument. other implantable instruments are independent to tachycardia, bradycardia, and fibrillation -- or it is used together and used and defibrillator, single, or duplex room PESA or such combination are included about this point. Furthermore, the approach of this invention can use the heart also for the instrument which is not stimulated at all or the instrument which is not transplantable. However, those tools must be what can sense or record the wave of the heart, in order to measure the section between each heartbeat of the heart. Using the electrode set to the patient, measurement of this section is remote operation from the heart, or can be performed from the interior of the heart itself, i.e., an atrium, the ventricle, or its both.

In order to ask for the heartbeat section between each continuation heart rate, the signal from the heart is transmitted to a heart stimulator or other same monitoring devices from an electrode. The sensing chip 52 or the sensing chip 62 senses the signal of the heart by drawing 1 . If these signals are detected, it will be promptly processed by various kinds of approaches, and the section between each heartbeat will be obtained. By U.S. Pat. No. 5,201,321 by Fulton entitled "the open diagnostic approach of the ease of starting to death-dealing arrhythmia and equipment" on April 13, 1993, a heartbeat signal is received and the approach and equipment which calculate the section between each heartbeat are explained. As an example, it is a signal from the heart.

It digitizes and the output is given to the peak detector connected to memory. A peak detector measures the timing of peak amplitude called A-A, P-P, V-V, or the R-R section of a heart signal. (Time amount during the continuation atrium depolarization which measured the A-A section out of the atrium.) The P-P section is the time amount during the continuation atrium depolarization measured from a patient's body. The V-V section is the time amount during the continuation

ventricle depolarization measured from the cardiac interior of a room. The R-R section is the time amount during the continuation ventricle depolarization measured from a patient's body. If it does so, memory or a recording device will memorize the timing of the continuation section. The timing section is usually measured by the measurement size between a time basis or a heartbeat. The specific approach or the equipment used for record of the section between each heartbeat is not so important, and these sections should just be obtained by accuracy.

If it can do, the section between each heartbeat will be recording during the time amount of the appointed die length, or a disease period. With a typical disease period, it continues for several minutes (for example, for 5 minutes), and between assignment heart rates, for example, 100 to 1000 heart rates. The die length of a disease period can be programmed and is not uniform. Rather, the section between each heartbeat is carrying out continuation disease period record continually.

The overall operating instructions and the overall algorithm of this invention are illustrated by explanation of the following system diagram. A system diagram expresses the program structure which operates a microprocessor 12 suitably. A program structure is created with the computer language of a low like an assembly, and is stored in the memory in a micro processor.

A program structure is first started by 100 at drawing 2 . As block 102 shows, the existing initialization procedure is performed. The clearance of setting out of all pointers, a register, and a counter and a specific memory location is included in these procedures. As block 104 shows, a disease period statistical data is chosen as a degree. This statistical data usually contains a well-known thing in count and a statistics algorithm, a variable, an equation, and these other contractors. Typically, this statistical data contains extent of a central tendency or variation in at least one and any combination. As an additional example of the statistics variable and equation which are calculated about each disease period, an average, MAD (average absolute deviation), a median, the mode (heart rate fluctuation section which occurs most frequently), the mode amplitude (percent to which the mode happens), the fluctuation range (difference of the highest and the minimum heart rate fluctuation section), PNN50 (percent of the heart rate fluctuation section of the time amount for 50ms or more), standard deviation, the range, a power-spectrum consistency, and distribution are mentioned.

A patient's heart rate fluctuation is evaluated, and in order to predict a patient's heart condition subsequently, sensing data are added to a statistical data. Disease period sensor data are chosen about block 106. Sensing data are obtained from the sensor or electrode which measures a patient's physiological condition. Such a sensor is used for sensing, such as evoked QT section, breathing, stroke volume, venae-centrales-hepatis oxygenation, a right ventricle pressure, blood pressure, a muscular noise, acceleration, an impedance, activity or motion, temperature, a hydrogen ion exponent in blood, and adrenaline, for example. If an activity sensor is taken for an example, a motion and actuation of a patient's body can be measured.

It is used for assessment of heart rate fluctuation combining a statistics type / algorithm, and sensing data. For example, a statistics type is used independently, or it includes in a statistics algorithm and is used for the statistics data origination of an assignment disease period. Next, a statistical data is combined with sensing data. Statistics and sensing data are set and form the disease period data of an assignment disease period.

A heart rate fluctuation zone and a corresponding cure are specified as block 108, and memory memorizes. A heart rate fluctuation zone defines a patient's normal and abnormal-cardiac-rate fluctuation. Drawing 3 shows relative arrangement of the typical heart rate fluctuation zone usually seen by 120. Three separate shafts define relative arrangement of 120. The average of AA section defines a x axis, PNN50 defines the y-axis, and a motion of a patient defines the z-axis. Within relative arrangement of 120, an abnormal-cardiac-rate fluctuation zone is usually shown by 122. The normal heart rate fluctuation zone 124 happens out of the boundary of the abnormality zone 122. The parameter of a lot defines the boundary or limitation of the abnormality zone 122 and the normal zone 124. The range of each value of three shafts or a value is included in these parameters. Preferably, a parameter divides the abnormality zone 122 into two or more heart rate fluctuation subzones. Drawing 3 re-divides the abnormality zone 122 into six different subzones 126-131, respectively. Two or more separate independent parameter groups define each subzone 126-131. Each subzone corresponds to a different heart rate fluctuation condition, and a subzone takes a

hierarchy format about the heart condition that a patient corresponds, concerning the abnormality level of heart rate fluctuation. For example, the subzone 126 expresses the heart rate fluctuation condition which shows caution of higher extent compared with the subzone 129.
The rectangular configuration expresses each subzone with drawing 3 a little. These configurations are offered so that it may be useful to explanation, and they change with the parameter which defines the boundary of a subzone. Moreover, a configuration is determined by the statistics, not only the data of a sensor but each patient's specific physiological condition, and requirement which were usually chosen as the definition of a subzone. Each patient who has received this point and heart rate fluctuation analysis needs the parameter of a different group which defines each subzone 126-131. Furthermore, a subzone may have the parameter with which plurality differs. Three different parameters define the abnormality zone 122 as drawing 3 . The number of parameters changes with 1 to 4, or 5 or more. For example, the 4th parameter can call it the time amount of the day. The configuration 120 shows three parameters and six subzones as an object for explanation.
The boundary or limitation of a parameter about each subzone is set up before heart rate fluctuation analysis initiation. For example, a medical practitioner or a clinician specifies a specific numeric value as each subzone based on a patient's medical hysteresis. Or a patient is supervised in order to decide the limitation of abnormalities and normal heart rate fluctuation. The monitor of a patient's heart rate fluctuation is carried out with the Holter monitor or other instruments which are used for heart rate fluctuation record and storage. Then, the limitation of each subzone is calculated based on this data. As an alternative, the boundary which appoints a subzone uses the first anticipation as the base, and has the approach of programming beforehand in memory.
There is a related cure in each subzone. If it can do, as for a cure, what has a hierarchy format about the heart condition that the abnormality level in heart rate fluctuation or a patient corresponds is good. It is this point and not corresponding in the subzone of the heart rate fluctuation which should be welcomed more positively, but assigning a therapy more positive to the subzone of more unusual heart rate fluctuation.
Drawing 4 usually expresses the typical cure for 150. The cure 150 is equipped with eight different therapy level called 152 -159 level in this drawing. Then, when it starts with the approach which is not positiveness most, the therapy level 152 needs initiation of the test or the data collection procedure of consuming more energy, in order are more good, namely, to judge a patient's heart condition to accuracy more. Various kinds of additional supervisory format, such as starting the sensor which senses a motion of ventilation, acceleration, an impedance, and the body or actuation, oxygen, blood pressure, temperature, blood oxygenation, the hydrogen ion exponent in blood, or adrenaline, is included in these procedures. Furthermore, a sampling rate is increased to these procedures and wave-like storage, the increment in the biopotential difference channel bandwidth for a diagnosis, the increment in parameter record, and the increment in level of diagnostic-data collection called the increment in signal processing are included in them. Moreover, count of an additional statistical data or the activity of an additional statistics algorithm is also performed. This statistical data is based at the heartbeat section memorized during the disease period current or last time. Moreover, initiation of the procedure which does not invade into the body thoroughly is also possible. For example, it is emitting warning or an alarm to a patient, a healthy provider, a clinician, or the appointed location. If the example of such warning is given, the heart condition in which the patient drew near will be notified, or warning a clinician about a patient's condition or the need for additional caution instead will be mentioned. Next, bradycardia pacing or anti-bradycardia pacing is needed on the therapy level 153. If heart rate fluctuation is more unusual as the therapy level 154 shows, exaggerated drive pacing of high rate will be carried out more. If level 155 shows anti-bradycardia pacing, for example, the patient senses atrium palpitation or the ventricular tachycardia, anti-bradycardia pacing will happen. The following higher level 156 needs the format of a nerve stimulus, in order to stimulate a patient's vagus nerve activity. Level 157 shows activation of the dosage of a neutralizer. In order to neutralize the increment in adrenaline, a chemical is poured into a patient with a chemical perfusion pump, and it acts also as a tranquilizer. Thus, a chemical normalizes heart rate fluctuation effectively. If the patient senses the severer heart condition, a cardioversion shock will be started as level 158 shows. On the severe level 159, when a patient expresses a severer heart condition or severe abnormal-cardiac-rate fluctuation is shown, it is

necessary to give the shock of a defibrillator.
Alternative activation of a cure 150 serves as energy saving, and serves as economization of power. Severe caution is not usually carried out until this point and a patient show abnormal-cardiac-rate fluctuation.
Detection of abnormality fluctuation starts a cure as shown in level 152-159. Speaking of [as already explained] a possible approach, additional sensing, and count and others are contained. In order to require power for enforcing these approaches, alternative activation serves as energy saving. Furthermore, the count and the diagnostic activities which are performed in the disease period of abnormal-cardiac-rate fluctuation and within a stimulator and which are not by any means required decrease the potential cause of active jamming, and it is suspended whether it is interrupted in order to centralize a count resource on heart rate fluctuation, or the monitor and diagnosis of a heart stroke, or they are not started. For example, when abnormal-cardiac-rate fluctuation is detected, amelioration of an unnecessary defibrillator capacitor is stopped.
Each therapy level 152-159 corresponds to a different heart rate fluctuation subzone. For example, again, according to drawing 3 , the subzone 126 corresponds to the therapy level 152, and the subzone 131 corresponds to the therapy level 159. Although drawing 4 has illustrated one cure, an alternative cure changes with patient individuals, and it is created so that a specific heart requirement may be satisfied.
Moreover, heart rate measurement and the assessment plan of other classes can also be used. For example, time amount domain analysis or count domain analysis are the two approaches of often using it, in case a researcher considers heart rate fluctuation. The graph expresses the R-R section with time amount domain analysis typically as a heart rate generated in specific time amount. There is an ECG monitor as an example, and this records and calculates heart rate fluctuation. In count domain analysis, a Fourier transform algorithm decomposes the R-R section as the sum total of a sinusoid function one by one. A graph expresses the result of this algorithm typically and shows the amplitude of heart rate fluctuation of the patient in different oscillation frequency. Since a certain frequency band in spectral analysis is connected with the autonomic nerve system of a nodus-sinuatrialis period, count domain analysis is dramatically advantageous depending on a certain case. Work "count domain measurement of heart rate fluctuation [after myocardial infarction], and the death rate" circulation besides J Thomas BIGGA Refer to 85th volume (1992) 164 -171 pages.
The program structure which calculates the selected disease period statistical data is shown by drawing 5 . A program structure starts in 170 and begins the existing initialization procedure by 172. Measurement of a continuation heart rate signal starts as shown next in the block 174.
If it does so, the section between a patient's heartbeats will be calculated so that it may be expressed with 176. These sections express the time amount between continuation heartbeats. Memory memorizes the section, as block 178 shows. And in order that the time die length of the section between heartbeats may determine 50ms or more and the following, block 180 investigates. It is equal to the section between heartbeats, or 50ms, or with it [more than], the increment of the counter is carried out by 182. If the section between heartbeats is lower than 50ms, the increment of the counter will be carried out by 184. Two or more counters are in a microprocessor or a control circuit, and the section between heartbeats counts the count 50ms or more and in the single disease period when it is the following. Examination determines whether the disease period expired with block 186. When the disease period has not expired, a program structure continues the section measurement between return and a continuation heartbeat to block 174. If the disease period has expired, as shown in 188, a statistical data will be calculated about the disease period. The statistical data calculated by 188 is calculated about the data collected during the disease period. As drawing 3 shows, PNN50 and an average are included in a statistical data. When a statistical data is calculated, it is stored in memory as block 190 shows. In addition to the statistics data storage of a current disease period, the timing of the 1 or 2 count sections and the time amount of the day are also stored again. Again, the program structure of drawing 5 begins to Measure the heartbeat section, so that it may be shown along a line 192, and it calculates the statistical data of the next disease period.
About drawing 6 , a program structure starts a patient's selection sensing and count of sensing data. A program structure starts in 200 and starts the existing initialization procedure by 202. As block 204 shows, the selected sensor is started and information gathering of a current disease period is

begun. As explained previously, various kinds of sensing equipments sense and the data from a patient are collected. Drawing 3 shows starting of acceleration, activity, or a sensor of operation. Next, in order to determine whether the disease period expired, block 206 investigates. When the disease period has not expired, a program structure continues return and information gathering to block 204. In disease period termination, a program structure progresses to block 208 and two or more sensors chosen with block 204 calculate the sensing data of the disease period. For example, an average activity ratio is obtained in quest of the average of the activity signal received during the disease period. As block 210 shows, memory memorizes sensing data and the time amount of the day. The program structure of drawing 6 starts sensing by two or more sensors chosen again in the end of a disease period repeatedly so that it may be shown along a line 212.

The program structure of the heart rate fluctuation zone correction already stored in memory is shown in drawing 7 . A heart rate fluctuation zone is automatically created according to an individual's physiological and cardiology-condition. A program structure starts in 216 and progresses to the block 218 which specifies disease period data collection and heart rate fluctuation measured-value acquisition. The disease period data containing sensing and a statistical data are collected and calculated as drawing 2 , and 5 and 6 explained. Measurement of heart rate fluctuation is obtained from disease period data. Measurement of this fluctuation expresses the individual in that disease period, or extent of heart rate fluctuation of a candidate, and contains the data or the selected part in all disease periods. Next, it investigates about whether it reached in the end of a disease period with block 220. When an answer is negative, disease period data collection is continued. When an answer is affirmative, it investigates whether a program structure continues to block 222 and current heart rate fluctuation measured value is in an abnormal-cardiac-rate fluctuation zone. Drawing 3 shows this motion. Three shafts (averages AA and PNN50 and motion of the body) determine the abnormal-cardiac-rate fluctuation zone 122 and the normal heart rate fluctuation zone 124 as a graphic display. Heart rate fluctuation measurement opts for a patient's heart rate fluctuation in a current heart condition and a current current disease period as compared with zones 122 and 124. If the current measured value of heart rate fluctuation is in the abnormal-cardiac-rate fluctuation zone 122, the corresponding therapy will be started as block 224 shows. For example, drawing 3 shows the possible location 226 in the subzone 128. If there is no current measured value of heart rate fluctuation into the abnormal-cardiac-rate fluctuation zone 122, reversely [the], examination of block 228 will be conducted. Drawing 3 shows the location 230 which has the possibility outside the boundary of the abnormality zone 122 in the normal zone 124.

Block 228 investigates whether the stimulator or the measuring instrument detected a certain abnormality heart condition. For example, a heart stroke was detected, or a stimulator may be in a consolidation alarm, may have warned of it or sensed a certain condition, and may have started the therapy. For example, the patient may be suffered from tachycardia, bradycardia, fibrillation, dysrhythmia, and arrhythmia and others. When the answer to block 228 is negative, a program structure progresses to block 232 and the disease period data containing heart rate fluctuation measured value are temporarily stored in memory. However, when the answer to block 228 is affirmative, the heart rate fluctuation zone configuration 120 of drawing 3 is corrected, and contains the heart rate variation and statistical data corresponding to the present disease period sensor. For example, correction includes the buildup or reduction of the boundary of the subzone 129-131 beyond one piece or it. And as block 236 shows, as for memory, disease period data and a heart rate variation are memorized.

Drawing 3 shows the location 238 which may not exist in the abnormality zone 122 at the beginning. therefore Although [a therapy is not performed by a patient's heart rate fluctuation data], when a stimulator or a measuring instrument detects an abnormality heart condition simultaneously, the stimulator itself begins to supervise [a therapy or] severe level. In this case, the parameter of the abnormality zone 122 changes and contains the parameter of a location 238. Drawing 8 shows the occurrence of the parameter of the subzone 129 being expanded and including a location 238.

The retentive memory of correction heart rate fluctuation zone configuration 120' containing correction subzone 129' is carried out to memory. Next, a subsequent heart rate variation is compared with correction configuration 120'.

In order to determine a patient's heart condition, the program structure in comparison with the

disease period data already memorized in the present disease period data is shown in drawing 9 . The already memorized disease period data express the case where a patient experiences a heart stroke or a certain abnormality heart condition. So, the comparison with the disease period data already remembered to be current disease period data is useful to recurrence precognition by fits and starts. Generating of a heart stroke means that a patient's heart has experienced the abnormalities in the heart.

Such abnormalities are caught as indication which may have for example, abnormality heart rhythm, heart complication, or the tense abnormality heart condition. As an example of abnormalities, arrhythmia, dysrhythmia, fibrillation, tachycardia, bradycardia, a coarse adjustment, myocardial infarction, cardiopathy, etc. are included.

A program structure starts in 250 and progresses to the block 252 which specifies disease period data collection and heart rate fluctuation measured-value acquisition. Drawing 2 , and 5 and 6 explain collection and count of disease period data. Next, it investigates about whether it reached in the end of a disease period with block 254. When an answer is negative, the loop formation of the program structure is carried out to block 252, and disease period data are collected succeedingly. When an answer is affirmative, a program structure investigates whether a heart stroke occurred following block 256. If a heart stroke occurs, memory will memorize disease period data, as block 258 shows. Drawing 10 Storing of this disease period data is shown.

Drawing 10 shows the typical heart rate fluctuation zone configuration 270 it have an average AA value in a x axis, and has breathing of the y-axis and a patient for MAD in the z-axis. Two assumption disease period series is shown in its them 274 and 276. The disease period series 274 contains two or more heart rate fluctuation measured value shown in 278-282. Measured value 278-282 expresses two or more disease period data locations which result in the heart stroke which measured value 282 shows. The disease period series 276 shows two or more heart rate fluctuation measured value shown in 284-288 which results in the heart stroke which a location 288 expresses. Each measured value includes other all information or parts which were collected and memorized during disease period data and the corresponding disease period. The disease period series 274 is the bradycardia fit of a location 282, and may already have been ended. A path 290 expresses an abnormal-cardiac-rate fluctuation path or a zone, and is shown as a line which results in measured value 282. The disease period series 276 is the tachycardia fit of measured value 288, and may already have been ended. The path 292 is shown as a line which results in this measured value. Each heart rate fluctuation paths 290 and 292 are expanded so that an abnormal-cardiac-rate allowance zone may be included as shown by 294 and 296, respectively. The allowance zones 294 and 296 expand paths 290 and 292, and they offer a large limitation or a large boundary rather than it determines the disease period series which results in a heart stroke. An allowance zone just expands paths 290 and 292 20% from 10%.

The disease period series 274 and 276 offers the path which can be foreknown in which a subsequent heart stroke happens through it. This point and a patient individual may experience many heart strokes within a specific disease period. The case where there is a desirable or common path which results in a specific fit in two or the fit beyond it can be considered. although it starts on the measurement location from which two separate heart strokes differed -- a common zone -- or it may progress through a common zone A part or overlapping altogether actually have a path. Such, the memorized path is compared with a current path and serves as an aid of future heart stroke precognition, or an aid of recognition of current fit generating.

Furthermore, the heterogenesis of the heart stroke is carried out, or it progresses over longer time amount. When a fit happens, the current disease period data in which the fit is shown are stored in permanent storage. Moreover, the retentive memory also of the front disease period data is carried out to memory. Thus, memory stores a series of disease period data, if a heart stroke happens. The amount and number of disease period data before memorizing are influenced by the time die length of for example, memory allocation usabiilty and a disease period, or the compressibility of data. If it can do, it is desirable to memorize the disease period data in front of divisor time amount after heart stroke generating.

When comparing with the disease period series which had the current disease period memorized, the time amount of a disease period generating day also becomes a factor. Disease period data show the

variation of about 24 time periods in a specific period. For example, an average heart rate, an average respiratory minute volume (namely, indication of a metabolic turnover demand), and mean activity fall during sleeping of an individual, and PNN50 and an average absolute deviation become high in comparison. If an individual awakes out of sleep and is working, a thing called mean activity will become comparatively high, and PN50 and an average absolute deviation will become comparatively low at motion, an average heart rate, an average respiratory minute volume, and it. As another factor, little fluctuation exists in a higher heart rate. For example, the man of the heart rate of 100bpm performs many sympathetic nerve activities rather than it controls a vagus nerve activity by the example. In this condition, a patient's heart rate fluctuation is dramatically low as expected. When a heart rate is maintained by 100bpm(s) and it carries out heart rate fluctuation by the activity of pacing, effectiveness is hardly produced.

Now, to examination of block 256, if the answer is affirmative, as it is shown in block 258 and explanation was made in the relation of drawing 10 , the retentive memory of the disease period data will be carried out to memory, as it already explained that it returned to drawing 9 . If the answer is negative, as block 300 shows, the comparison with the disease period series remembered to be the current measured value of heart rate fluctuation will be performed. And it investigates whether it agrees with the disease period series the current measured value of heart rate fluctuation of block 302 was remembered to be. When not agreeing, disease period data are stored temporarily as shown by block 304. If it agrees, block 306 shows that the suitable therapy was started.

Drawing 10 shows the comparison with the disease period series remembered to be the present measured value of heart rate fluctuation. The disease period series 307 has the measured value 308, 310, and 312 of three pieces of heart rate fluctuation. The measured value of two pieces or locations 308 and 310 are shown in the outside of a path 290, the boundary of the allowance zone 294, a limitation or a path 292 and the boundary of the allowance zone 296, or a limitation. Therefore, it does not agree with the disease period series the measured value of these two pieces was remembered to be by both. However, since measured value 312 is in the boundary of the allowance zone 294, agreement exists in measured value 312 and the disease period series 274.

It will be started if it agrees with the disease period data with which the current measured value of heart rate fluctuation was memorized also by class like a cure throat. Drawing 4 shows an alternative therapy. The same therapy started from the first during generating of the memorized disease period series as one possibility is started again. For example, since the measured value 304 of drawing 10 is in the boundary of the allowance zone 294, measured value 279 or the same therapy started by 278 may be started. The cure for the technique of not being moderate and positive is also possible. In this case, high caution and caution of energy cost are more enough. For example, an additional sensor may be started or you may transmit by warning or the alarm. As an alternative, the positiveness of a cure is based on the latency of the fit come later. For example, although possibly it resulted in the slow ventricular tachycardia, since that was not right, the path 274 was not fatal for the patient. Possibly anti-tachycardia pacing was enough for the arrhythmia fit therapy. The same cure can be used.

there is nothing in above-mentioned equipment and an above-mentioned approach about modification which exists without deviating from the range of this invention -- since ****** is possible, it was contained in explanation, or no matters shown with the attached drawing must not be interpreted as instantiation, and must not be caught in the sense of definition.

[Translation done.]